REMARKS

Favorable consideration and allowance of the present application is respectfully requested.

Claims 1-5, 10-29, and 32, including independent claims 1, 19, and 24, are currently pending in the present application. Independent claim 1, for instance, is directed to a method for treating a wound by removing a protease from the site of the wound. The method comprises selecting a protein-containing fibrous component capable of removing a protease. The protein-containing fibrous material consists essentially of protein fibers. A wound dressing is formed from the protein-containing fibrous component. At least one protein is selected from the group consisting of growth factors, cytokines, and chemokines for application to a wound site. The wound dressing and protein are applied to the wound site so that the protein-containing fibrous component is in contact with the wound site. At least a portion of the protease found at the wound site is allowed to be attracted to and entrapped by the protein-containing fibrous component. The wound dressing is removed from the wound site so that at least a portion of the protease is removed from the wound site.

In the Office Action, independent claims 1, 19, and 24 were initially rejected under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent No. 6,156,334 to Meyer-Ingold, et al. in view of WO 97/07273 to Ninagawa. Meyer-Ingold, et al. is directed to a wound covering for initiating or promoting healing of chronic wounds. Specifically, the wound covering is characterized in that substances which interact with interfering factors present in the wound exudates are covalently bonded to a carrier material. As

correctly noted by the Examiner, however, Meyer-Ingold, et al. fails to disclose a carrier material (wound dressing) that consists essentially of protein fibers. Nevertheless, Ninagawa was combined with Meyer-Ingold, et al. in an attempt to render obvious independent claims 1, 19, and 24. Specifically, the Office Action indicates that it would have been obvious to use the nonwoven fabric of Ninagawa as the carrier material simply because any known wound covering may be utilized in Meyer-Ingold, et al.

However, Applicants note that the level of skill in the art cannot be relied upon to provide the suggestion to combine references. *M.P.E.P. § 2143.01.* Moreover, an allegation that modifications of the prior art would have been well within the ordinary skill of the art because all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *M.P.E.P. § 2143.*01. In the instant case, the Office Action has merely indicated that it is well known to use silk fabrics. Even if true, no objective motivation or suggestion would have been provided to utilize the particular nonwoven fabric of Ninagawa in Meyer-Ingold, et al. Instead, it appears that the rationale for the proposed combination is based only on the notion that it would have been "obvious to try", which is clearly improper under *35 U.S.C. §103(a).* For instance, although cursorily mentioning a cotton-wool wound covering, the preferred carrier materials of Meyer-Ingold, et al. are said to include cellulose, alginates and other polysaccharides, and synthetic polymers. (Col. 8, ll. 27-44).

Nevertheless, even if Meyer-Ingold, et al. and Ninagawa are somehow combined as suggested in the Office Action, the resulting combination would still fail to disclose or

suggest certain aspects of independent claims 1, 19, and 24. For example, regardless of the carrier material utilized, Meyer-Ingold, et al. expressly requires that it be covalently modified with trapper molecules, such as antibodies, chelators, enzyme inhibitors, enzymes, enzyme mimics, peptides, and other proteins. The trapper molecules possess the desired specificity for removing the interfering factor from the wound. For instance, Meyer-Ingold, et al. emphasizes that it is of "great importance" that the trapper molecules be covalently bonded to the wound covering for the wound dressing to "function as intended." (Col. 8, ll. 1-3). Likewise, Meyer-Ingold, et al. also states the following:

> The advantage of the invention lies in the fact that a selective removal of the interfering factors is possible by the substances covalently bonded to the carrier material . . . . (Emphasis added) (Col. 2, ll. 66-67 and Col. 3, ll. 1-4).

Thus, it is readily apparent that the covalent bonding of trapper molecules to a carrier material is a critical and indispensable requirement of Meyer-Ingold, et al. This is in direct contrast to the present claims. Namely, independent claims 1, 19, and 24 require that the protein-containing fibrous component consists essentially of protein fibers. As stated in Applicants' previous response, the fibrous component is thus limited to protein fibers, to the exclusion of non-protein fibers. This limitation also excludes fibers obtained by activating protein fibers with the trapper molecules of Meyer-Ingold, et al. Specifically, the claimed fibrous component consisting essentially of protein fibers may accomplish the desired protease removal without requiring the extra step of activating the fibers with trapper molecules.

Applicants emphasize that neither of the cited references recognize the benefits obtained by the claimed invention. For instance, as noted above, independent claims 1, 19, and 24 expressly require a fibrous component that "consists essentially of protein fibers." It has been discovered that protein fibers may absorb and remove various proteases from wound sites. Specifically, it is believed that proteases are able to tunnel into the interior of the wound dressing because the protein fibers, or specific regions thereof, are substrates for the targeted protease. Hence, the protease cuts into the fiber, thereby moving away from the surface and effectively becoming removed from the equilibrium process at the fiber surface. In this manner, such deleterious proteases may be permanently and disproportionately removed from the wound site. Accordingly, for at least the reasons set forth above, Applicants respectfully submit that independent claims 1, 19, and 24 patentably define over the above-cited references, taken singularly or in any proper combination.

In the Office Action, independent claims 1 and 24 were also rejected under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent No. 6,156,334 to Meyer-Ingold, et al. in view of U.S. Patent No. 5,447,505 to Valentine, et al. Specifically, the Office Action indicates that Valentine, et al. also discloses the use of wool, for instance, to treat wounds. However, Valentine, et al. fails to cure any of the defects discussed above. For at least this reason, Applicants respectfully submit that independent claims 1 and 24 patentably define over the above-cited references, taken singularly or in any proper combination.

Finally, independent claims 1 and 19 were also rejected under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent Publication 2002/064551 to Edwards, et al. in view of Ninagawa and U.S. Patent No. 5,158,555 to Porzilli. However, Applicants previously submitted the declaration of Jason P. McDevitt, which established conception of the claimed invention prior to the earliest claimed priority date of Edwards, et al. (February 29, 2000).[1] Thus, Edwards, et al. is not available as prior art to the present application and may not be used in the proposed *§ 103* rejection.

Applicants also respectfully submit that, at least for the reasons indicated above relating to the corresponding independent claims 1, 19, and 24, dependent claims 2-5, 10-18, 20-23, 25-29, and 32 patentably define over the references cited. However, Applicants also note that the patentability of such dependent claims does not necessarily hinge on the patentability of the respective independent claims. In particular, some or all of these claims may possess features that are independently patentable, regardless of the patentably of the independent claims.

Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Lewis is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this response.

Please charge any additional fees required by this Response to Deposit Account No. 04-1403.

---

[1] Applicants' submission of this declaration is in no way an admission that Edwards, et al. either anticipates the claims of the present application under any applicable section of 35 U.S.C. § 102 or renders obvious, alone or in combination with other reference(s), the claims of the present application under 35 U.S.C. § 103.

Respectfully submitted,

DORITY & MANNING, P.A.

Jason W. Johnston
Registration No.: 45,675

DORITY & MANNING, P.A.
P.O. Box 1449
Greenville, SC 29602-1449
Phone: (864) 271-1592
Facsimile: (864) 233-7342

Date: 8/2/04